DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

ETEX Corporation
Michael Strunk, Ph.D.
Director of Research
675 Massachusetts Avenue
Cambridge, Massachusetts 02139

Re: K132868
Trade/Device Name: ETEX CarriCell® Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 22, 2015
Received: January 23, 2015

Dear Dr. Strunk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132868

Device Name
ETEX CarriCell® Bone Substitute Material

Indications for Use *(Describe)*
CarriCell® is indicated for filling bone voids or defects of the skeletal system (i.e., extremities and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CarriCell® may be hydrated with saline or autologous blood prior to implantation. CarriCell® is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter: ETEX Corporation
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Date Prepared: February 17, 2015

Product Code(s): MQV (21 CFR §888.3045)

Device Class: II (21 CFR §888.3045)

Classification Panel: Orthopaedics

Classification Name: Filler, Bone Void, Calcium Compound (21 CFR §888.3045)

Proprietary Name: CarriCell® Bone Substitute Material

Predicate Device(s): EquivaBone® Osteoinductive Bone Graft Substitute cleared per K063050 (ETEX Corporation)
CarriGen® Porous Bone Substitute Material cleared per K062630 (ETEX Corporation)
PROGENIX® DBM Putty per K060794 (Medtronic Sofamor Danek)

Device Description: CarriCell® Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of hydration solution to form a putty. No mixing is required. The putty can be administered to the treatment site by syringe or manual application. The material can be shaped into a desired form prior to implantation. After the putty is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order with a chemical and crystalline structure similar to that of natural bone minerals. CarriCell® Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use: CarriCell® is indicated for filling bone voids or defects of the skeletal system (i.e., extremities and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CarriCell® may be hydrated with saline or autologous blood prior to implantation. CarriCell® is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate biomaterial, sodium alginate, and sodium carboxymethylcellulose (CMC).

Predicate Comparison: The following table summarizes the specific technological characteristic similarities and differences between CarriCell® and the cited predicate devices.

	CarriCell® Bone Substitute Material	**EquivaBone® Osteoinductive Bone Graft Substitute**	**CarriGen® Porous Bone Substitute Material**	**PROGENIX® DBM Putty**
K-Number	K132868	K063050	K062630	K060794
Product Code	MQV	MQV	MQV	MQV
Classification	21 CFR §888.3045	21 CFR §888.3045	21 CFR §888.3045	21 CFR §888.3045
Materials	93% Calcium Phosphate 5 % CMC 2% Sodium Alginate	45% Calcium Phosphate 5 % CMC carboxymethyl cellulose 50% DBM demineralized bone matrix	91.5% Calcium Phosphate 3.5 % CMC 5% EfferSoda™	Demineralized bone matrix, bovine collagen, sodium alginate
Ca:P ratio	1.22 ± 0.06	1.65 ± 0.05	1.40 ± 0.02	N/A
Physical Form	Moldable or Injectable Paste	Moldable Paste	Moldable or Injectable Paste	Injectable DBM in Alginate/Collagen Matrix
Product Design	Self-setting calcium phosphate material with CMC and sodium alginate that hardens in aqueous environment at 37° C.	Self-setting calcium phosphate material with CMC and Demineralized Bone Matrix (DBM) that hardens in aqueous environment at 37°C.	Self-setting calcium phosphate material with CMC and EfferSoda that hardens in aqueous environment at 37°C.	Demineralized Bone Matrix (DBM) in a sodium alginate gel carrier.
Kit Sizes	1cc to 20cc	1cc to 20cc	1cc to 20cc	N/A

Sterilization	Gamma Irradiation for an SAL of 10^{-6}	Gamma Irradiation for an SAL of 10^{-6}	Gamma Irradiation for an SAL of 10^{-6}	N/A
Pyrogenicity	Non-Pyrogenic per USP <85>	Non-Pyrogenic per USP <85>	Non-Pyrogenic per USP <85>	N/A

Performance Data: Testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted.

An in-vivo study was performed as part of the assessment of the subject CarriCell® device. This study assessed the performance of the material in a femoral core defect model. The study concluded that CarriCell® material did perform as intended with proper osteointegration with host bone.

Non-clinical in-vitro bench testing included crystalline phase analysis, elemental analysis, chemical identity, pH, setting temperature, morphology, and mechanical properties. Biocompatibility of the device has been established in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and Testing.

Performance data and in-vivo animal studies have demonstrated that CarriCell® is efficacious as a standalone bone graft substitute, mixed with either saline or autologous blood.

Conclusions: The conclusions drawn from the nonclinical and clinical tests demonstrate that the CarriCell® device is as safe, as effective, and performs as well as or better than the predicate device.